REMARKS

This application has been reviewed in light of the Office Action dated May 26, 2005. Claims 18-28 are pending in the application. Claims 1-17 were canceled in a previous amendment. Claims 18, 19, 21-23, and 28 are amended in a manner that Applicant believes overcomes the rejections in the Office Action. Applicant believes that the originally submitted claims are patentable over the materials relied upon by the Examiner. However, claims 18, 19, 21-23, and 28 are amended for clarification purposes only. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicant is believed to be entitled. Applicant submits that no new matter or issues are introduced by the amendments.

Applicant respectfully submits that in view of the amendments and remarks herein, all claims presently pending in the application are allowable.

Claim Rejections – 35 U.S.C. § 103

In the Office Action, claims 18-28 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,136,362 to Ashton (Ashton '362) in view of U.S. Patent No. 5,403,564 to Katschnig et al. (Katschnig '564).

However, it is respectfully submitted that in light of the amended claims provided herein claims 18-28 clearly and patentably distinguish over Ashton '362 in view of Katschnig '564.

Referring to FIGS. 1 through 11, Ashton '362 shows a high temperature time pasteurization system and method of cleaning. Ashton clearly does not teach a system capable of sterilizing any processed material, but in contrast teaches a pasteurization system. (Underlining for emphasis.)

Ashton, teaches a heating system separated from a holding line or tube. Ashton also teaches heating by a material which changes state, i.e. water changing to steam, but that material is used to warm water for subsequently warming milk (to less than the boiling point of water)

rather than to process effluent (col. 6, lines 59-62). While Ashton teaches a method and apparatus for thermal decontamination, the process disclosed by Ashton is far removed from sterilizing to a desired SAL. For example, Ashton discloses steam as an agent to increase temperature of milk, but milk is only taught to be raised to a pasteurization level, and, in fact, Ashton only teaches a system for pasteurizing.

In Webster's Third New International Dictionary copyrighted 1993, *pasteurization* is defined as:

> **pasteurization** - 1.: a method devised by Pasteur to check fermentation (as in wine or milk) involving the partial sterilization of a substance (as a fluid) at a temperature and for a length of time that does not greatly change its chemical composition but does destroy many pathogenic organisms and other undesirable bacteria though spores and thermoduric organisms (as lactic acid bacteria)survive. 2.: the use of electricity, hot water , or steam to bring soil (as in a greenhouse bench) to a temperature of 180° F for a period of 30 minutes in order to kill nematodes, weed seeds, and various fungi and bacteria - compare STERILIZATION.
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> *Sterilization is defined as:*
> **sterilization** - 1: the act or process of sterilizing: as a: the rendering of a body or material free from living cells and esp. microorganisms usu. By killing those present (as by heat) - ...

Pasteurization and sterilization are clearly not the same and require different apparatus in the processing thereof.

Ashton teaches raising material to a temperature less than boiling (e.g. 162° F) while the invention of the Applicant operates at temperatures (and pressures) which are above the boiling temperature of water (e.g. 140-150° centigrade) while maintaining water in a liquid state. For this reason, it is difficult to understand how Ashton might apply to a device for sterilizing to a predetermined SAL, as Ashton teaches a device which is not required to raise liquid above a boiling level or to keep water in a liquid state while raised to a temperature above the boiling point. So while Ashton is a flow through system, it does not include, teach nor suggest valves, pathways and processes which are associated with sterilization. It is noted that the Examiner mentions a pressure relief flow restriction means, which acts to ensure that pressure maintains a forward flow of liquid. In devices associated with the instant invention, pressure is maintained at such a high level that no valve is required for such a purpose, but, rather, only one valve is used

to impede volumetric flow from a sterilization path. Of course, generally, fluid flow systems utilize temperature sensing and pressure sensing and valve means which are opened and closed in response to sensed parameters, but requirements of pasteurization are dramatically different from requirements of sterilization. For this reason, it is not considered obvious to employ of Ashton in sterilization, especially in the case of a system for sterilizing water.

Referring to FIGS. 1 and 2, Katschnig '564 shows an apparatus for heating thermally decontaminating pumpable or pourable material. The apparatus of Katschnig includes a microwave unit for heating and two pumps for maintaining pressure in an unheated holding line 13 which is downstream from a treatment chamber 3 in a microwave unit 1. Katshnig also teaches a control unit 24 for receiving a pressure signal which measures pressure in the holding line and is operatively connected to both pumps. Katshnig clearly teaches and claims the need for two pumps and a control unit therefor. Moreover, two temperature sensors are employed in the Katschnig apparatus, a first sensor 27 which is upstream of holding line 13 and a second temperature sensor 28 which is downstream from holding line 13 is connected to central control unit 24 which, in turn, sends corrections for additional or lesser energy requirements of microwave device 1, a signal which is detected after heating of fluid effluent from holding line 13. It is understood from Figure 2 and the specification that reflux may be an issue (col. 3, lines 64-68 and col. 4, lines 1-12). Such is the case where energy is supplied in one vessel, while holding is provided in another vessel.

Katschnig, on the other hand, teaches a microwave based device. To make the microwave device operable, Katschniq teaches away from Applicant's invention by requiring two pumps, to maintain necessary pressures and flow rates, where a device according to Applicant's invention may only use one pump or even none in some embodiments. Further, Katschnig teaches permitting non-decontaminated material to exit the treatment line to be reprocessed (e.g. from column 3, lines 34-36, ... *The control valve 33 is further linked to a conduit 34 by which not yet decontaminated material can be returned to the reservoir 9.* No such material may exit the pressure/sensor controlled valve of Applicant's invention, therefore maintaining the integrity of sterilized effluent in the downstream portion of the system.

In contrast, amended claim 18 of the present application recites, *inter alia*, "aqueous liquid purification apparatus for sterilizing liquid to a target SAL ...

a flow through reservoir comprising ... an enclosed, elongated flow path along which liquid is displaced and disposed for being heated to a sterilizing temperature ...

heating chamber pathways comprising sidewalls capable of withstanding increased internal pressure generated by ... liquid being heated to the sterilizing temperature while being kept in a liquid state ...

heating chamber comprising media ... being heated to a critical predetermined temperature consistent with heating liquid within the heating chamber pathway to the sterilizing temperature ...

a flow resisting element, disposed in the output pathway, which restricts effluent flow ... maintains a predetermined minimum upstream pressure within the internal heating chamber pathway ...

a temperature sensor switch ... activated to an ON state when liquid in the heating chamber pathway is at a first predetermined temperature ...

a pressure sensor switch disposed in the heating chamber pathway ... activated to an ON state when pressure in the heating chamber is at least a first determined pressure consistent with sterilization dynamics ...

a valve which is in an OPEN state only when said temperature sensor switch is in an ON state and said pressure sensor switch is in an ON state " (Underlining added for emphasis.)

Moreover, amended claim 28 of the present application recites similar claims to apparatus provided and the following steps, *inter alia*, "delivering liquid into the apparatus at a rate which is consistent with a desired SAL value ...

applying heat to the heating chamber pathway ...

opening the valve to permit effluent flow of sterilized liquid only when the temperature

sensor switch is in an ON state and the pressure sensor switch is in an ON state"

Neither the Ashton '362 patent or the Katschnig '564 patent in any way discloses or suggests structure as recited in independent claims 18 or 28. Neither the Ashton '362 patent or the Katschnig '564 patent disclose or suggest, the claimed elements of this instant invention recited supra.

In addressing the question of whether or not the present invention is obvious or nonobvious under Section 103, it is important that several factors be carefully weighed. First, case law requires that the Examiner engage in a "problem" analysis to determine whether or not the prior art addresses the same problem or a different problem than that which confronted the inventor prior to making the present invention. Hindsight reconstruction of the prior art based upon confidential access to the present application is not available to establish obviousness.

The problem confronting the present inventor was to see if the limitations of the prior art could be overcome or substantially alleviated. Specifically, the inventor hoped to find a way of sterilizing liquids at temperatures well over the boiling point of water. The inventor was able to do so, whereas Ashton did not. As an example, high temperature, short time pasteurization system in Ashton means use of a 162° F heat process, which is far below vaporization temperature of water. (See column 5, line 30-45.)

If it is the Examiner's contention that the prior art addresses Applicant's problems and provide Applicant's solutions, it is respectfully requested that the Examiner identify the locations in the references relied on where Applicant's problems and solutions are mentioned and addressed.

More specifically, "the relationship between the problem which the inventor . . . was attempting to solve and the problem to which any prior art reference is directed" is highly relevant. Stanley Works v. McKinney Manufacturing Co., 216 USPQ 298, 304 (Del. D.C. 1981). Thus, in analyzing the prior art under Section 103 of the Act, we must clearly comprehend the problems addressed by the present inventor and such must be compared or contrasted, as the case may be, with the problem addressed by the prior art.

In respect to the applicability of any reference against claims of a pending U.S. patent application, the Examiner's attention is directed to In re Gibbons, 100 USPQ 398, where it is stated:

> In considering the question of invention, it is necessary to determine whether or not the art relied upon contains adequate directions for the practice of the invention without resort to the involved application. (Emphasis added.)

The Examiner is courteously requested to find where in the references relied upon the requisite "adequate directions" are provided by the prior art relied on sufficient to reach the presently claimed combination. Since the prior art relied upon is neither intended nor able to achieve what the Applicant has achieved, as set forth in the presently pending claims, it is respectfully submitted that no directions whatever are provided by the references which would lead to the present invention, as claimed. Accordingly, the references should be accurately construed and withdrawn.

The pertinent primary inquiries in determining obviousness under Section 103 are set forth in the Supreme Court's decision in Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). The primary considerations set forth therein require (1) determination of the scope and content of the prior art; (2) identification as to the differences between the prior art and the claims at issue; and (3) resolution of the level of ordinary skill in the pertinent art.

In respect to the scope of the prior art and the differences standards, the Section 103 criteria provided by In re Winslow, 151 USPQ 48 (CCPA 1966) is that the prior art must address and provide the inventor's answer to the particular problem confronting an inventor. Here, the references relied upon by the Examiner do not propose, expressly or inferentially or by sound reasoning, the claimed solution to the inventor's aforementioned problem. As an example, Katschnig teaches a requirement for two or more pumps while Ashton teaches pasteurization. Consequently, the references fail the Winslow Section 103 test.

In Orthopedic Company, Inc. v. United States, 217 USPQ 193 (Fed. Cir. 1983), the Federal Circuit set forth a useful guide for determining the scope and content of the prior art. Orthopedic, at pages 196, 197, also focuses on the "problem" faced by the inventor:

> In determining the relevant art . . . one looks at the nature of the problem confronting the inventor.
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> . . . would it then be nonobvious to this person of ordinary skill in the art to coordinate these elements in the same manner as the claims in suit? The difficulty which attaches to all honest attempts to answer this question can be attributed to the strong temptation to rely on hindsight while undertaking this evaluation. It is wrong to use the patent in suit [the patent application before the Examiner] as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness. . . . (Emphasis added.)

Applying the Federal Circuit's analysis in Orthopedic, it is clear the claims of the present application are allowable under Section 103. Persons ordinarily skilled in sterilization otherwise in pasteurization would be charged only with an understanding of the express teachings of the individual references. The cited references do not expressly teach or suggest the claimed combination. To read into the references the inventor's present solution, necessarily requires hindsight reliance on Applicant's application, contrary to the instructions of Orthopedic.

The Federal Circuit has also said that "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." (Emphasis provided). Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick, 221 USPQ 481 (Fed. Cir. 1984). The above standard was reiterated in Fromson v. Advance Offset Plate, Inc., 225 USPQ 26 (Fed. Cir. 1985). Clearly, the present combination and methodology as set forth in the present claims are not obvious "as a whole" from the references.

The Board of Appeals confirms that hindsight reliance through confidential access to an application being examined, in an attempt to arrive at the claimed invention under 35 U.S.C. Section 103, is negated. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. of App. 1985), which states:

> To support the conclusion that the claimed combination is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed combination or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. (Emphasis supplied).

Here, there is no express or implied suggestion in the references that the claimed combination or method could or should be used to solve the problem facing the present inventor. There is no convincing line of reasoning available in respect to the references by which an artisan would, as a matter of obviousness, have arrived at the present claimed invention absent any suggestion, express or implied, in the reference of the solution fashioned by the present inventor, as set forth in the claims.

Here, the indication of nonobviousness is substantial, under the primary considerations of Graham, i.e., the basic irrelevance of the prior art to the claimed combination, failure of others to provide the inventor's solution both before and after the present invention and the fact that others have not foreseen the inventor's solution even though the prior art teachings have been around for some time. A determination of nonobviousness is compelling.

Nonobviousness follows from Panduit Corp. v. Dennison Manufacturing Co., 1 USPQ 2d 1593, 1605 (Fed. Cir. 1987):

> Indeed, that the elements noted by the court lay about in the prior art available for years to all skilled workers, without, as the court found, suggesting anything like the claimed inventions, is itself evidence of nonobviousness. (Emphasis provided.)

Where, as here, the prior art is simply incapable of functioning as required by the present claims and achieving what is achieved by the present invention, Section 103 rejections cannot be sustained. Here as in Ex parte Gould, 231 USPQ 943, 946 (Bd. App. 1986):

> . . . the examiner has failed to make out a prima facie case that . . . [the prior art] achieved or is capable of achieving . . . [what is achieved by the present invention] we are constrained to reverse the rejections based on . . . [the prior art]. (Emphasis supplied.)

For the Examiner to assign attributes to the references which do not, in fact, exist and to entirely discount the critical language within the claims which is directed to Applicant's combination does not comply with the Graham requirement of [objectively] identifying the differences between the claimed invention and the prior art. Under In re Wood and Eversole, 202 USPQ 171, 174 (CCPA 1979), it was necessary:

> . . . to more closely approximate the reality of the circumstances surrounding the making of an invention. . . . (Emphasis added.)

A brief examination of "hindsight" law as handed down by the Federal Circuit superimposed upon the facts of this case will be helpful.

See, for example, Union Carbide Corp. v. American Can Co., 220 USPQ 584, 591 (Fed. Cir. 1984):

> . . . helps us to guard against slipping into hindsight rather than viewing the question as the inventor at the time the patented device was developed." (Emphasis provided.)

The hindsight approach was further criticized in W. L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303, 312-313 (Fed. Cir. 1983):

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. (Emphasis added.)

Recently, the Federal Circuit repeated its prohibition against "hindsight." In Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 USPQ 2d 1434, 1438, 1439 (Fed. Cir. 1988), the Federal Circuit held:

> "When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination.
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> * * * *
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> There is no suggestion in any individual prior art reference of such a combination of location and configuration nor is it suggested by the prior art as a whole. ([I]t is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention).
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> * * * *
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> . . . the district court . . . does not show that there is any teaching or suggestion in any of the references, or in the prior art as a whole, that would lead one with ordinary skill in the art to make the combination.
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> * * * *
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> In view of the antithetical principles of operation and the absence of any teaching or suggestion to combine these prior art devices, there is no apparent basis for the district court's conclusion that it would have been obvious to one skilled in the art to make the combination. (Emphasis added; citations omitted.)

The Uniroyal analysis applies here as well.

Clearly, the present invention is not obvious, based upon the analysis of primary considerations mandated by the U.S. Supreme Court in Graham.

The rejection under Section 103 has a further malady. It fails to give any weight to the fact that the prior art patents teach away from the simplicity and reliability of the present invention. Here, as in In re Hedges, et al., 228 USPQ 685, 687 (Fed. Cir. 1986):

> "The totality of the prior art disclosures leads substantially away from the claimed invention". We agree with . . . [Applicant] that the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill. "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art". (Emphasis added; citations omitted.)

The present claims now contain substantial reference to intended use, intended purposes and intended function. While the claims do not depend upon statements of intended use or purposes or preamble for patentability, such statements are entitled to considerable weight.

Because of the above distinctions, it is respectfully submitted that claim 18-28 are patentable and not obvious over Ashton '362 in view of Katschnig '564. Reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 18 -28, presently pending in the application are believed to be in condition for allowance. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicant. Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 19-3542. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 19-3542 therefor.

Respectfully submitted,

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